IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE UNITED STATES OF AMERICA	)	
	)	
Plaintiff,	)	Civil Action No. _____
	)	
v.	)	**COMPLAINT**
	)	
CENTER FOR INTERVENTIONAL PAIN AND SPINE LLC and CHEE H. WOO	)	**JURY TRIAL DEMANDED**
	)	
Defendants.	)	

COMPLAINT OF THE UNITED STATES OF AMERICA

The United States of America, by and through David C. Weiss, United States Attorney for the District of Delaware, and Shamoor Anis and Jacob Laksin, Assistant United States Attorneys for the District of Delaware, alleges as follows:

INTRODUCTION

1. The United States of America brings this action pursuant to the False Claims Act ("FCA"), 31 U.S.C. §§ 3729 *et seq.*, and under common law and equitable theories of payment by mistake and unjust enrichment, against defendants Center for Interventional Pain and Spine LLC ("CIPS") and Chee H. Woo, M.D. ("Dr. Woo") (collectively, "Defendants"), to recover treble damages and penalties resulting from Defendants' unlawful conduct, including the submission of false claims to Medicare, Medicaid, and the Federal Employees Health Benefit Program ("FEHBP") (collectively "Federal Healthcare Programs") for services that were not reasonable and necessary.

2. As described below, between July of 2018 and at least 2021, CIPS, through Dr. Woo, devised and executed a scheme to illegally profit from urine drug testing ("UDT") by performing UDT for patients regardless of whether the testing was reasonable and necessary for

the diagnosis or treatment of any individual patient. CIPS routinely performed the testing even though the treating physicians had not ordered the UDT and, in many cases, were unaware that a urine sample had been collected.

3. At Dr. Woo's direction, CIPS's non-physician technicians and personnel routinely placed orders for, and CIPS's in-house laboratory performed, UDTs for nearly all of CIPS's patients, notwithstanding that CIPS' treating providers had neither determined that the UDT was appropriate nor ordered the testing.

4. In addition, CIPS simultaneously ordered both initial "presumptive" screening tests and confirmatory "definitive" tests even though the presumptive tests were not used to determine whether definitive testing was necessary and played no role in CIPS's medical decision-making.

5. Beginning in January 2019, CIPS expanded its unlawful testing practices by submitting thousands of false claims for psychological testing that was not performed or was not used in the treatment of its patients.

6. Through these and other practices, from at least July 2018 through at least 2021—and, upon information and belief, continuing through the present day—Defendants knowingly submitted and caused to be submitted millions of dollars in false claims to Federal Healthcare Programs for services that were not reasonable and necessary for treatment of their patients.

JURISDICTION

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1345, and 1367(a).

8. This Court may exercise personal jurisdiction over CIPS under 31 U.S.C. § 3732(a) because its principal office is located in the District of Delaware, it has transacted business in this District, and a substantial part of the events and omissions giving rise to the claims alleged occurred in this District.

9. This Court may exercise personal jurisdiction over Dr. Woo under 31 U.S.C. § 3732(a) because he has transacted business in this District and because a substantial part of the events and omissions giving rise to the claims alleged occurred in this District.

10. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1395(a), because Defendants transact business in this District, and a substantial part of the events giving rise to this action occurred in this District.

PARTIES

11. The United States brings this action on behalf of the Department of Health and Human Services ("HHS"), which, through the Centers for Medicare and Medicaid Services ("CMS"), administers Medicare and Medicaid; and on behalf of the Office of Personnel Management ("OPM"), which funds and oversees the Federal Employees Health Benefit Program ("FEHBP").

12. Defendant Dr. Woo is a resident of Wayne, Pennsylvania, and a physician licensed to practice medicine in Delaware. At all times relevant to the Complaint, Dr. Woo was CIPS's director and president.

13. At all times relevant to the Complaint, CIPS has been a limited liability corporation authorized and existing under the laws of the State of Delaware, with its principal place of business at 3401 Brandywine Parkway, Wilmington, Delaware, 19803, and satellite offices in Wilmington, Delaware; Middletown, Delaware; Newark, Delaware; Milford, Delaware; Horsham, Pennsylvania; Fort Washington, Pennsylvania; Willow Grove, Pennsylvania; Bryn Mawr, Pennsylvania; Exton, Pennsylvania; Lancaster, Pennsylvania; Harleysville, Pennsylvania; and Wyomissing, Pennsylvania.

LEGAL AND REGULATORY FRAMEWORK

I. The False Claims Act

14. The FCA provides, in pertinent part, that any person who:

> (a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim

is liable to the United States for three times the amount of damages which the Government sustains, plus a mandatory civil penalty of not less than $13,946 and not more than $27,894 per violation. 31 U.S.C. § 3729(a); 28 C.F.R. § 85.5.

15. For purposes of the FCA,

> the terms "knowing" and "knowingly" (A) mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud. . . .

31 U.S.C. § 3729(b)(1).

16. The term "claim" includes any

> request or demand . . . for money or property . . . that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program . . . and if the United States Government (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

31 U.S.C. § 3729(b)(2).

17. The FCA defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

18. "A claim can be proven 'false' in two ways: factually, when the facts contained within the claim are untrue, and legally, when the claimant falsely certifies that it has complied

with a statute or regulation the compliance with which is a condition for Government payment." *United States v. Care Alternatives*, 952 F.3d 89, 96 (3d Cir. 2020) (alterations and quotation marks omitted).

II. The Medicare Program

19. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain health care services. *See* 42 U.S.C. §§ 1395 *et seq*.

20. Medicare entitlement is based on age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426-1, 426A. Medicare-insured individuals are commonly referred to as Medicare "beneficiaries."

21. The Medicare program consists of four parts: A, B, C, and D. 42 U.S.C. §§ 1395c-1395i. Medicare Part B covers outpatient care, including, *inter alia*, physician services and ancillary services, such as clinical laboratory services, furnished by physicians and other providers and suppliers.[1] 42 U.S.C. § 1395k.

22. As alleged herein, Defendants submitted, or caused to be submitted, false claims under Medicare Part B.

A. The Medicare Part B Program

23. Medicare Part B covers only those services, including diagnostic laboratory services, which are reasonable and necessary for the diagnosis or treatment of an illness or injury. *See* 42 U.S.C. § 1395y(a)(1)(A) ("[N]o payment may be made under [Medicare] part A or part B . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary

[1] In the relevant regulations, physicians and other practitioners are generally referred to as "suppliers" in the Medicare program, rather than "providers." *See* 42 C.F.R. § 400.202. This Complaint nonetheless uses the common term "provider" to refer to individual practitioners.

for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]"); 42 C.F.R. § 411.15(k) (disallowing payment for certain types of services, tests, and examinations that are not "reasonable and necessary"). In order to receive payment, Medicare Part B providers must certify that services for which they bill Medicare are medically necessary. 42 C.F.R. § 424.24(g)(1).

24. The Secretary of HHS ("Secretary") is responsible for specifying services covered under the "reasonable and necessary" standard and has wide discretion in selecting the means for doing so. *See* 42 U.S.C. § 1395ff(a). The Secretary fulfills this responsibility both through formal rulemaking and through other forms of guidance.

25. HHS provides guidance to eligible providers pursuant to a series of Manuals, published by CMS, which are available to the public, including on the Internet. *See generally*, CMS Manuals, *available at* https://www.cms.gov/medicare/regulations-guidance/manuals (last visited May 30, 2024) (hereinafter "CMS Manuals").

26. CMS engages private contractors, referred to as Medicare Administrative Contractors ("MACs"), to review and pay claims submitted by health care providers. 42 U.S.C. §§1395u, 1395kk-1. MACs generally act on behalf of CMS within a specified jurisdiction to process and pay Medicare claims submitted by health care providers.

27. At all times relevant to this Complaint, Novitas Solutions, Inc. ("Novitas Solutions") was the MAC responsible for processing Medicare Part B claims in Delaware and Pennsylvania.

28. MACs also issue Local Coverage Determinations ("LCDs") which identify, for the states within their jurisdiction, procedures and services that are reasonable and necessary, and therefore eligible for payment under Medicare. 42 U.S.C. § 1395ff(f)(2); *see also id.* § 1395m-1(g).

29. Health care providers who wish to submit claims for Medicare reimbursement must enroll in the Medicare program. As part of the enrollment process, and as a condition of participation in Medicare, providers must certify compliance with Medicare regulations, and program instructions and conditions. *See* 42 C.F.R. § 424.510. Enrolled providers also must certify that they meet, and will continue to meet, the requirements of the Social Security Act as well as Medicare regulations, and the conditions regarding coverage for services for which they seek reimbursement. 42 C.F.R. § 424.516(a)(1).

30. Participating providers must properly document in the patient's medical record the service or procedure performed. 42 C.F.R. § 410.32(d).

31. To participate in the Medicare program, group practices and clinical laboratories must submit a Medicare Enrollment Application, Form CMS-855B.

32. Form CMS-855B requires, among other things, that signatories certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me . . . . The Medicare laws, regulations, and program instructions are available through the Medicare Administrative Contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions . . . . I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

See https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855b.pdf (last visited May 30, 2024).

33. An authorized official must sign the "Certification Statement" in Section 15 of Form CMS-855B, which "legally and financially binds [the] supplier to the laws, regulations, and program instructions of the Medicare program." *Id.*

34. Once the provider is enrolled or credentialed, the provider may submit claims to Medicare for services rendered to beneficiaries.

35. The National Provider Identifier ("NPI") is a standard and unique health identifier for health care providers. All providers and practitioners must have an assigned NPI number prior to enrolling in Medicare.

36. Typically, physicians are compensated for the services they provide Medicare patients on a fee-for-service basis as determined by Medicare's fee schedule. 42 U.S.C. § 1395w–4. To obtain compensation, physicians must deliver a compensable service and certify that the service was medically necessary.

37. The Medicare statute requires that each claim submitted for an item or service payable under Medicare Part B include the name and NPI for the referring physician. 42 U.S.C. § 1395l(q)(1).

38. To obtain Medicare reimbursement for certain outpatient items or services, providers and suppliers must submit a claim form known as the CMS 1500 form ("CMS 1500") or its electronic equivalent, known as the 837P format. 42 C.F.R. § 424.32.

39. Among the information the provider or supplier must include on a CMS 1500 or through the 837P format are certain diagnostic codes, including Current Procedural Terminology Codes ("CPT codes") and Healthcare Common Procedure Coding System ("HCPCS") Level II codes, that identify the services rendered and for which reimbursement is sought. Each code corresponds to a specific service.

40. When submitting claims to Medicare on the CMS 1500, providers must certify, *inter alia*, that (a) "the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE;" (b) the

information on the claim form is "true, accurate, and complete;" and (c) the provider understands that "payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of material fact, may be prosecuted under applicable Federal and State laws." CMS 1500 also requires providers to acknowledge that: "Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties." *See* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1500.pdf (last visited May 29, 2024).

41. Health care providers who submit claims electronically using the 837P format must also execute an Electronic Data Interchange Enrollment Form ("EDI Enrollment Form") with CMS. At all times relevant to the Complaint, an EDI Enrollment Form to electronically bill Medicare executed by CIPS was on file with Novitas Solutions. By executing the EDI Enrollment Form, CIPS certified that it would "be responsible for all Medicare claims submitted to CMS or a designated CMS contractor by itself, its employees, or its agents," and to "submit claims that are accurate, complete, and truthful."

42. By executing an EDI Enrollment Form, CIPS also acknowledged "that all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program, and that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim as required by this Agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law." *Id.*

43. A provider has a duty to familiarize itself with the statutes, regulations, and guidelines regarding coverage and reimbursement for the Medicare services it provides. *See Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 64 (1984).

44. Generally, once a provider submits a CMS 1500, or the electronic equivalent, to the Medicare program, the claim is paid directly to the provider, in reliance on the foregoing certifications, without any review of supporting documentation, including medical records.

45. CIPS billed Medicare under Part B for medical services including, but not limited to, clinical laboratory services furnished by physicians and other providers, by submitting claims for reimbursement on the CMS 1500 or the 837P format to Novitas Solutions. CIPS received payment from Medicare as a direct result of these submissions.

III. The Delaware Medicaid Program

46. Delaware's Medicaid program, known as the Delaware Medical Assistance Program ("DMAP"), is authorized by Title XIX of the Social Security Act. 42 U.S.C. §§ 1396 *et seq.* Medicaid is a joint federal-state program that provides health care benefits, including laboratory services coverage, for certain groups including the poor and disabled. Each state must have a single state agency to administer the Medicaid program. 42 U.S.C. § 1396a.

47. Delaware's Department of Health and Social Services, Division of Medicaid and Medical Assistance ("DMMA") administers the DMAP and receives, processes, and pays claims for services under the Medicaid program. HHS reimburses DMMA for the federal share of all qualified Medicaid claims and ensures that the state complies with minimum standards in the administration of the program.

48. Health care providers bill DMAP for services provided to Medicaid beneficiaries by submitting claim forms electronically to DMMA through its fiscal agent, Hewlett Packard Enterprise.

49. To participate in the Delaware Medicaid program and receive payment for services rendered, health care providers must enter into a contract with the DMAP, called the Contract for

Items or Services Delivered to Delaware Medical Assistance Program Eligibles in the Department of Health and Social Services ("DMAP Contract").

50. The DMAP Contract provides that when a healthcare service provider submits a claim for payment for items or services rendered under the DMAP, the provider certifies that the items or services comply with DMAP rules, regulations, policies, and procedures, including that the services rendered were medically necessary, and that all information and documentation submitted by the provider in support of a claim for payment is true, accurate, and complete. Providers also certify that non-compliance with DMAP rules, regulations, and policies may result in the denial of payment and the imposition of penalties.

51. DMMA issues Medicaid policies, manuals, and other materials to provide guidance to providers regarding which services are reimbursable by Medicaid and how to bill those services. *See* 42 C.F.R. § 431.18.

52. DMAP's General Policy Manual instructs that providers must direct patients "to the most appropriate, medically necessary, and cost-efficient care possible," and maintain documentation supporting the services rendered. Providers are also "responsible for the accuracy, truthfulness, and completeness of all claims submitted to DMAP." Providers engage in "fraud" and "abuse" in connection with the DMAP if they "attempt to obtain or provide services that are not medically necessary." *See Delaware Health and Social Services Division of Medicaid & Medical Assistance, Delaware Medical Assistance Program General Policy Manual* §§ 1.6, 1.10 1.14, 1.20, *available at* https://medicaidpublications.dhss.delaware.gov/docs/DesktopModules/Bring2mind/DMX/API/Entries/Download?Command=Core_Download&EntryId=897&language=en-US&PortalId=0&TabId=94 (last visited on June 3, 2024).

53. CIPS billed DMAP for medical services including, but not limited to, clinical laboratory services by submitting claims for reimbursement to DMAP through its fiscal agent. CIPS received payment from DMAP as a direct result of these submissions.

IV. FEHBP

54. Congress established the FEHBP to provide health benefits to civilian federal employees. *See generally* 5 U.S.C. § 8901 *et seq.* The FEHBP is administered by OPM, which, in turn, contracts with various health insurance carriers to provide services to FEHBP members and their families. *See id.* §§ 8902, 8909(a). The OPM makes payments to the insurance carriers for services rendered to FEHPB members using funds from the Employee Benefits Fund, which the United States Treasury holds and invests. *Id.* § 8909.

55. As a condition of funding, the FEHBP requires that covered services be medically necessary to prevent, diagnose, or treat an illness, disease, injury or condition.

56. CIPS submitted claims to health insurance carriers in the FEHBP program for reimbursement for services rendered to federal government employees and their families. CIPS received payment from FEHBP insurers as a direct result of these submissions.

V. Urine Drug Testing

A. Regulatory Requirements for Laboratory Test Services

57. Laboratory services, including diagnostic laboratory tests, must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), 42 U.S.C. § 263a, as set forth at 42 C.F.R. Part 493.

58. Medicare regulations require that (1) laboratory tests must be ordered by the physician treating the patient for a specific illness or injury; (2) laboratory test orders that are not individualized to patient need (or for which the need is not documented in the patient chart) are

not covered services; and (3) claims for such laboratory services that do not meet these requirements are ineligible for payment and must be denied. *See* 42 C.F.R. § 410.32.

59. Pursuant to 42 C.F.R. § 410.32(a), all diagnostic tests "*must be ordered by the physician who is treating the beneficiary*, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem *and who uses the results* in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." (emphasis added).

60. According to CMS's Medicare Benefit Policy Manual ("MBPM") "Requirements for Ordering and Following Orders for Diagnostic Tests, . . . the physician must clearly document, in the medical record his or her intent that the test be performed." MPBM, Ch. 15, § 80.6.1 (issued Aug. 29, 2008).

61. Medicare requires proper and complete documentation of the services rendered to beneficiaries:

> No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

42 U.S.C. § 1395l(e). As described above, the Delaware Medicaid program, DMAP, imposes similar requirements.

62. Medicare regulations expressly state that a laboratory's claim for a service will be denied if there is insufficient documentation in the patient's medical record to establish that the service was reasonable and necessary. 42 C.F.R. § 410.32(d)(3)(ii).

63. The Department of Health and Human Services, Office of Inspector General ("HHS-OIG") also published *Compliance Program Guidance for Clinical Laboratories* in the

Federal Register. 63 Fed. Reg. 45076 (Aug. 24, 1998), *available at* https://www.oig.hhs.gov/authorities/docs/cpglab.pdf (last visited May 30, 2024). Among other things, the HHS-OIG clinical laboratory guidance directs that providers must conduct and document a patient-specific assessment of necessity for each test ordered: "Medicare will only pay for tests that meet the Medicare coverage criteria and are reasonable and necessary to treat or diagnose an individual patient. . . . Medicare may deny payment for a test . . . which does not meet the Medicare coverage criteria (e.g., done for screening purposes) or where documentation in the entire patient record . . . does not support that the tests were reasonable or necessary for a given patient." *Id.* at 45079.

64. The Medicare Claims Processing Manual similarly instructs that "[laboratory t]ests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered except when there is a statutory provision that explicitly covers tests for screening as described." *See* Medicare Claims Processing Manual, Ch. 16, § 120.1, *available at* https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c16.pdf (last visited May 30, 2024).

B. Types of Urine Drug Tests

65. Urine drug testing ("UDT") is used to determine the presence or absence of drugs or metabolites, *i.e.*, a byproduct of a drug after it is metabolized by the body.

66. UDT is performed in a number of contexts. In the clinical pain management context—particularly in the case of management through long-term opioid use—drug testing is often used to monitor whether patients are taking prescribed drugs and adhering to treatment. The tests are used both to confirm that patients are taking, rather than diverting, the drugs that are prescribed to them, and that they are not taking other drugs not prescribed by the treating physician.

67. UDT can be divided into two categories: presumptive and definitive. Presumptive UDT (sometimes referred to as "screening" testing) is used to determine the presence or absence of drugs or drug classes in a urine sample. Definitive UDT (sometimes referred to as "confirmatory" testing) is used when necessary to confirm the results of presumptive testing by identifying the presence of specific drugs or metabolites in the urine sample.

68. There are two primary methods of performing presumptive tests. These tests can be performed using a point of care ("POC") testing cup or test strips that are dipped into a urine sample. POC testing cups and test strips are relatively inexpensive and typically feature a panel of 11 or 12 treated strips, one for each drug or drug class being tested. When the strips are dipped into the urine specimen, a change in color signifies the presence or absence of the specific drug or drug class for which each strip tests. Using POC cups or strips, a provider can receive almost immediate results for the substances tested in his or her own office. Alternatively, presumptive tests can be performed by an immunoassay analyzer, a device found in laboratories and in some physicians' offices, which rapidly determines the presence or absence of the tested drugs. Immunoassay tests are generally reimbursed at higher levels than POC test cups and strips.

69. At all times relevant to the Complaint, CIPS owned an immunoassay analyzer and performed its own presumptive testing using that equipment. CIPS operated under CLIA certification numbers 08D2139181 and 39D2149361.

70. Presumptive UDT can be useful in making point of care decisions when the patient is present if the results are available at the time of the patient visit. It can also be used to determine the necessity of further confirmatory testing through definitive UDT, for instance, to rule out a false positive or to determine the concentration of a particular drug.

71. Definitive or confirmatory UDT is generally conducted in laboratories that can perform mass spectrometry and either gas or liquid chromatography. These testing methodologies can provide quantitative results, identifying the concentration of a drug or metabolite in a sample.

72. The equipment required to perform definitive UDT is more sophisticated, and more expensive, than the equipment for presumptive or screening tests. Most treating providers do not have the specialized laboratory equipment needed to perform definitive testing themselves. Instead, treating providers typically refer definitive drug testing to independent laboratories.

73. Definitive testing is not indicated absent a clinical determination, documented in the patient record, that such testing is reasonable and necessary based on patient-specific indications.

74. "Chromatography generally is reserved for confirmatory or definitive testing when the initial [presumptive] results are unexpected." Raouf et al., *A Practical Guide to Urine Drug Monitoring.* FEDERAL PRACTITIONER, April 2018, at 41, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6368048/ (last visited May 30, 2024). For example, if a patient is prescribed a certain drug, a positive presumptive test result for that class of drug would be expected. If the test result is negative for that class of drug, however, and the patient insists that she is taking her medication as prescribed, a definitive laboratory test to "confirm" this unexpected negative result may be reasonable and necessary.

75. Similarly, if a patient's presumptive test yielded a positive result for a nonprescribed or illicit drug, then definitive UDT to evaluate this unexpected positive result may, under certain circumstances and depending on individual patient factors, be reasonable and necessary.

76. If a presumptive test is negative for an illicit drug or a drug not prescribed, and there is nothing in the patient's presentation or drug abuse history to indicate abuse of that drug,

then definitive UDT for that drug is not reasonable and necessary for the treatment and diagnosis of that patient.

77. As discussed below, beginning around July 2018, CIPS began performing its own definitive UDT, using mass spectrometry and liquid chromatography ("LCMS"). CIPS' LCMS machine enabled it to test urine specimens for numerous drugs and metabolites during a single run of a sample. CIPS used these in-house LCMS capabilities to bill the Federal Healthcare Programs for thousands of definitive UDTs that were not medically necessary.

78. Definitive UDT is covered by Federal Healthcare Programs only to the extent it is necessary for an individual patient, based on that individual's presumptive test results and other factors specific to that individual that are considered by the treating provider and documented in the patient's medical records. In other words, to be reasonable and necessary, definitive UDT must be based on an assessment of individual patient risk and cannot be ordered as a matter of course.

79. UDT guidelines published by the American Society of Interventional Pain Physicians ("ASIPP") recommend only a baseline screening or presumptive test at the initial visit and then adherence monitoring with "confirmation for accuracy with chromatography *in select cases.*" Manchikanti *et al.*, PAIN PHYSICIAN 2012; 15:S67-S116, ISSN 1533-3159, "ASIPP Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain."

80. ASIPP published in 2011, and reprinted in 2012, a diagram charting "algorithmic steps in urine drug testing in chronic pain." *Id.* at S92. The diagram recommends baseline testing at the point of care, using an immunoassay test. *If* there is an inappropriate or unexplained result, definitive testing is warranted for that result. If results are appropriate, no definitive testing is needed, and the algorithm suggests a *random* point of care (*i.e.*, immunoassay screening or presumptive) test in 1-3 months. And if the results of that test are appropriate, the algorithm suggests follow-up presumptive or screening test in 6-12 months. In short, definitive testing is

recommended only for unexplained results and even presumptive testing is recommended only as often as necessary based on the patient's prior testing history. *See generally id.*

81. Indeed, "it would be abusive to an economically strained health care system to routinely screen every patient at every visit." Owen *et al.*, *Urine drug testing: current recommendations and best practices*. PAIN PHYSICIAN, 2012; 15:ES126, *available at* https://www.painphysicianjournal.com/current/pdf?article=MTcxMA%3D%3D&journal=68 (last visited May 30, 2024).

C. LCD L35006

82. Local Coverage Determinations ("LCDs") are determinations issued by MACs that announce prospectively "whether or not a particular item or service is covered" by Medicare. 42 U.S.C. § 1395ff(f)(2)(B). LCDs specify the circumstances under which Medicare would deem certain procedures and services to be reasonable and necessary, and may also describe what documentation is needed to support reimbursement.

83. On or around October 1, 2015, Novitas Solutions issued Local Coverage Determination L35006, titled "Controlled Substance Monitoring and Drugs of Abuse Testing." ("LCD L35006"). Novitas Solutions made LCD L35006 available to all providers within its jurisdiction, which included Delaware and Pennsylvania.

84. LCD L35006 provides guidance regarding the appropriate indications for and expected frequency of presumptive and definitive UDT to be covered by Medicare.

85. LCD L35006 explains that presumptive UDT "may be ordered when it is necessary to rapidly obtain and integrate results into clinical assessment and treatment decisions." With regard to definitive UDT, LCD L35006 states: "[P]hysician-directed definitive profile testing is reasonable and necessary when ordered for a particular patient based upon historical use and community trends. However, the same physician defined profile is not reasonable and necessary

for every patient in a physician's practice. Definitive UDT orders should be individualized based on clinical history and risk assessment, and must be documented in the medical record."

86. LCD L35006 includes specific guidance for establishing and documenting medical necessity for UDT in pain management practice. Medical necessity for drug testing "must be based on patient-specific elements identified during the clinical assessment, and documented by the clinician in the patient's medical record[.]" At a minimum, the required documentation must include patient history, previous laboratory findings, and a risk assessment plan.

87. LCD L35006 also includes specific guidance regarding the expected frequency of UDT testing. Under the LCD, "[f]requency of testing beyond the baseline presumptive UDT must be based on individual patient needs substantiated by documentation in the patient's medical record." Moreover, the "frequency of testing must be based on a complete clinical assessment of the individual's risk potential for abuse and diversion using a validated risk assessment interview or questionnaire and should include the patient's response to prescribed medications and the side effects of medications."

88. LCD L35006 is clear that "Blanket Orders"—defined as "an identical order for all patients in a clinician's practice without individualized decision-making at every visit"—are "non-covered services" for which Medicare may not be billed. Other non-covered services set forth in the LCD include:

a) "Routine standing orders for all patients in a physician's practice are not reasonable and necessary."

b) "Reflex" testing is defined as "testing that is performed reflexively after initial test results to identify further diagnostic information essential to patient care."

89. "Reflex definitive UDT is not reasonable and necessary when presumptive testing is performed at point of care because the clinician may have sufficient information to manage the

patient. If the clinician is not satisfied, he/she must determine the clinical appropriateness of and order specific subsequent definitive testing (e.g., the patient admits to using a particular drug, or the IA [immunoassay] cut-off is set at such a point that is sufficiently low that the physician is satisfied with the presumptive test result)." LCD L35006 has been revised and published on several occasions, including most recently on or about October 17, 2019. However, the provisions of LCD L35006 referenced herein were in effect at all times relevant to the Complaint and remain in effect.

90. Defendants received LCD L35006 from Catalyst Lab Solutions, LLC ("Catalyst"), which provided administrative and management services to CIPS in connection with an in-house laboratory that CIPS used to perform UDT. On February 19, 2019, Gregory Gottheimer, Catalyst's president, emailed a copy of LCD L35006 directly to Dr. Woo. Upon information and belief, CIPS also received LCD L35006 directly from Novitas Solutions.

E. Reimbursements for Laboratory Tests

91. Medicare reimbursement rates for UDT vary significantly depending on the type of UDT.

92. At all times relevant to the Complaint, Medicare generally reimbursed presumptive UDT based on the methodology (analyzer versus POC test cup or strip) used by the physician practice or the complexity of the test under CLIA. During the time period relevant to the Complaint, POC tests were reimbursed by Medicare rates between $12 and $25 and analyzer tests were reimbursed by Medicare at rates between $60 and $100.

93. Effective January 1, 2016, CMS created four CPT codes for definitive UDT, G0480, G0481, G0482, and G0483, based on the number of drug classes tested. Only one of these four definitive UDT codes may be billed per patient per day. The following table defines these codes and their corresponding 2023 Medicare reimbursement amount:

Definitive UDT Code	Definition	2023 Medicare Reimbursement
G0480	Definitive drug testing for 1-7 drug classes, including metabolites.	$114.43
G0481	Definitive drug testing for 8-14 drug classes, including metabolites.	$156.59
G0482	Definitive drug testing for 15-21 drug classes, including metabolites.	$198.74
G0483	Definitive drug testing for 22 or more drug classes, including metabolites	$246.92

See id.; 2023 Clinical Diagnostic Laboratory Fee Schedule, available at https://www.cms.gov/license/ama?file=/files/zip/23CLABQ1.zip (last visited June 3, 2024).

VI. Psychological and Neuropsychological Testing

94. Psychological and neuropsychological tests are diagnostic tests used to assess a person's cognitive, emotional, and behavioral functioning. Such tests are used by clinicians to aid in the diagnosis and treatment of patients with known or suspected mental disorders or dysfunction. Psychological and neuropsychological testing can be billed using CPT 96138. The CPT code description for code 96138 is "psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes."

95. "Psychological and neuropsychological testing services utilize diagnostic tests when mental illness or brain dysfunction is suspected, and clarification is essential for the diagnosis and treatment." *Psychological and Neuropsychological Testing Codes for Psychologists,* available at https://www.apaservices.org/practice/reimbursement/health-

codes/testing#:~:text=Psychological%20and%20neuropsychological%20testing%20services,for%20the%20diagnosis%20and%20treatment (last visited May 31, 2024).

96. Like all diagnostic tests, psychological and neuropsychological tests are only reasonable and necessary where they are "ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." 42 C.F.R. § 410.32(a).

97. LCD L35101, which applies to services performed on or after October 1, 2015, specifies that "[t]esting conducted when no mental illness/disability is suspected is considered screening and is not covered by Medicare. Non-specific behaviors that do not suggest the possibility of mental illness or disability are not an acceptable indication for testing." Instead, "[e]ach test administered must be medically necessary. Standardized batteries of tests are only acceptable if each component test is medically necessary." *Id.*

98. Further, brief screening measures and use of other mental status exams in isolation is not classified as psychological or neuropsychological testing because such tests are typically part of a more general clinical exam or interview. *Id.* Additionally, routine re-evaluation of chronically disabled patients that is not required for a diagnosis or continued treatment is not considered medically reasonable and necessary and brief screening measures are not classified as covered psychological or neuropsychological testing. *Id.*

99. "Psychological and Neuropsychological testing is not considered reasonable and necessary when . . . [c]omprised exclusively of self-administered or self-scored inventories, or as screening tests of cognitive function or neurological disease (whether paper-and-pencil or computerized; e.g., AIMS, Folstein Mini-Mental Status Examination)." *2019 Psychological and*

Neuropsychological Testing Billing and Coding Guide, American Psychological Association Services, Inc. ("APA") at 7.

DEFENDANTS' FRAUDULENT UDT TESTING SCHEME

100. As detailed below, under the direction and control of Dr. Woo, CIPS submitted claims for reimbursement to the Federal Healthcare Programs that it falsely certified were reasonable and necessary. The certifications of medical necessity were false because (i) the UDTs were not ordered by treating physicians; (ii) the UDTs were ordered without individualized risk assessment of the patients; (iii) the patients' medical records did not document the necessity for the UDTs; and (iv) the UDT results were not used for diagnosis or treatment. Defendants knew, recklessly disregarded, or were willfully ignorant that their submissions were false.

101. From at least January 2018 to July 2020, CIPS implemented a UDT Protocol that was developed by Dr. Woo and applied to all CIPS patients ("UDT Protocol"). Pursuant to the UDT Protocol, CIPS's physicians did not order UDTs. Instead, the UDT Protocol required Urine Drug Sample technologists ("UDS Techs"), who were not physicians, to place orders for UDTs. This practice directly conflicts with Medicare regulations, which explicitly state that "[t]ests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." 42 C.F.R. § 410.32(a). Despite this, CIPS falsely certified on each of its submissions that the UDTs for which it was seeking reimbursement were reasonable and necessary.

102. Pursuant to the UDT Protocol, CIPS' UDS Techs routinely ordered both a presumptive screen and a definitive test (collectively, the "Default UDT"). The UDT Protocol did not allow the UDS Techs to only order presumptive UDT without also ordering a definitive UDT.

103. In addition to the presumptive screen, the definitive testing panel included in the Default UDT could be either a "standard" or "comprehensive" panel. Pursuant to the UDT Protocol, the UDT Techs ordered a standard or comprehensive definitive testing panel based upon

whether the patient was categorized as "moderate" risk or "high" risk. Under the UDT Protocol, patients were to be categorized as high risk if they were "consistently inconsistent, ha[d] a history of substance abuse, or [were] taking an extreme amount of prescribed medications." Moderate risk patients were to be tested using the standard panel and high risk patients were to be tested using the comprehensive panel.

104. The standard definitive testing panel corresponded to CPT billing code G0482. The comprehensive definitive testing panel corresponded to CPT billing code G0483. Although a panel for low risk patients, which corresponded to CPT billing code G0481, also existed, CIPS rarely used this panel. For example, between July 2018 and July 2020, CIPS billed Medicare using billing code G0481 a total of 47 times but submitted billing code G0482 a total of 2,118 times and billing code G0483 a total of 8,500 times.

105. The UDS Techs ordered the presumptive tests and definitive tests that comprised the Default UDT at the same time and on the same form.

106. The results of the presumptive tests were not available before patients were given prescriptions and left the office. CIPS' providers thus did not use the presumptive results to inform the course of treatment for patients.

107. The results for the presumptive tests also were not available before definitive tests were ordered. CIPS's providers therefore could not have used presumptive tests to determine the need for definitive testing or to document the medical necessity of the definitive UDT, as required under LCD L35006 and other guidance.

108. CIPS' UDT Protocol, which has been in effect and enforced from July 2018 and, upon information and belief, remains in place to the present day, requires the Default UDT for all new patients and for all established patients every three months, regardless of the patient's individualized risk assessment or clinical presentation. The UDT Protocol also requires UDS

Techs to order a Default UDT the following month if a patient's presumptive UDT returned an inconsistent result, regardless of any individualized assessment of patient need. CIPS ordered testing based on the UDT Protocol even though LCD L35006 and Medicare regulations prohibit the use of such blanket orders.

109. CIPS's UDT Protocol did require physicians to assess their patients' risk. However, the physicians at CIPS, including Dr. Woo, routinely failed to perform any risk assessment prior to ordering UDTs, and some had no knowledge of UDTs being ordered for their patients. Further, the physicians' notes in their patients' medical records often did not contain any "documentation of medical necessity" for the patients' UDTs, contrary to the explicit requirements of 42 C.F.R. § 410.32(d)(2).

110. In July 2018, Catalyst's laboratory supervisor, Kiersten DeBlaker, confirmed in an email to CIPS that "collectors" rather than physicians were ordering presumptive and confirmation testing, and urged CIPS to develop a "proper protocol" on how physicians "will assess each patient."

111. Despite DeBlaker's urging, however, CIPS continued to have non-physicians order UDTs. In a July 19, 2018 email to her boss at Catalyst, DeBlaker lamented that "it keeps getting lost" in her conversations with CIPS that "the doctors are responsible for risk assessing each patient." The following month, DeBlaker again cautioned CIPS that "it is not up to the lab to risk assess the patients. It is up to the physicians to risk assess every patient, at every appointment." DeBlaker suggested that CIPS physicians should "start risk assessing [CIPS] patients in September or October."

112. CIPS did not follow DeBlaker's advice.

113. Instead of individualized assessments of patient risk by physicians, as the guidance required, UDS Techs at CIPS automatically categorized a patient as high risk if that patient:

a. Had a single previous inconsistency in their UDT results;
b. Was prescribed a benzodiazepine;
c. Was prescribed >50mg of morphine;[2] or
d. Had a PMP overdose risk score >200.

114. Not only was the failure of CIPS physicians to individually risk assess their patients inconsistent with the guidance regarding medical necessity, it also frequently resulted in patients being categorized as "high risk" by UDS Techs in circumstances where such a classification obviously lacked any medical basis. For example, on several occasions, new CIPS patients were tested for drugs that had been prescribed the same day by the treating CIPS physician. Although these patients had not yet received the medication, let alone consumed and metabolized it, their UDT was classified as one that yielded "inconsistent" results because metabolites that "should have" been in their urine were not present. As a result, the patients were classified as "high risk" by the UDS Techs and tested using the "comprehensive" definitive testing panel. Further, because the patients were not subsequently risk assessed by the physician, and because the UDT Protocol called for patients to be classified as high risk if they had ever had an inconsistent result, they continued to be tested using the "comprehensive" panel on each visit.

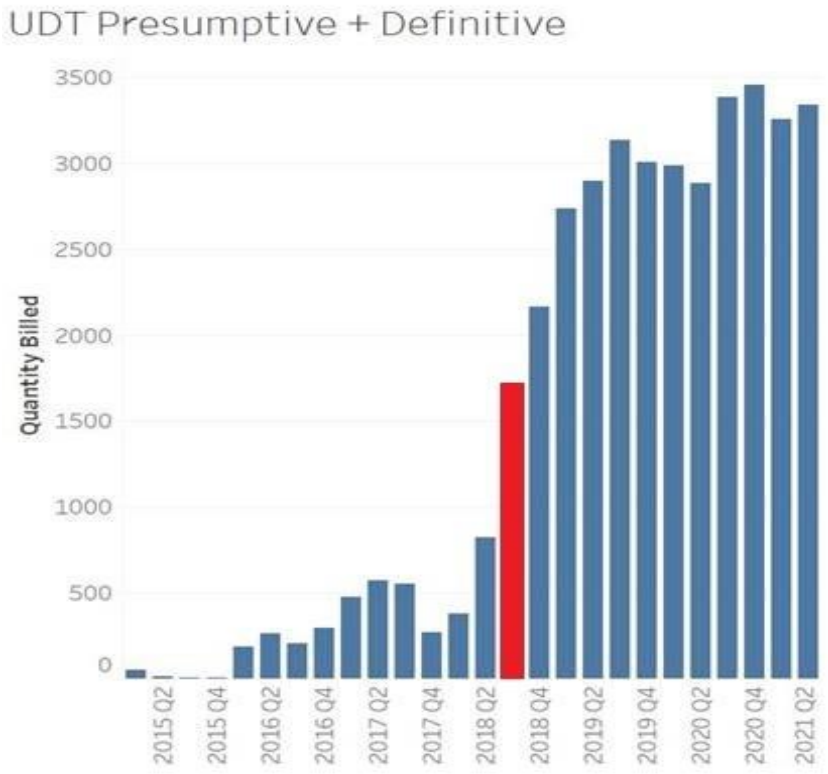
115. Under the UDT Protocol, CIPS conducted and billed Medicare for thousands of presumptive and definitive UDTs that were not reasonable and necessary.

116. CIPS and Dr. Woo directly benefited from this practice. In 2018, in an effort to profit from its UDT practices, CIPS acquired its own Liquid Chromatography Mass Spectrometry ("LCMS") machine. Once the machine was operational and certified, in or around July 2018,

[2] The strength of opioid medications is often measured in terms of morphine milligram equivalents or MMEs. *See, e.g.*, Opioid Oral Morphine Milligram Equivalent (MME) Conversion Factors, available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/Opioid%20Morphine%20EQ%20Conversion%20Factors%20%28vFeb%202018%29.pdf (last visited May 31, 2024).

CIPS began performing and being reimbursed by the Federal Healthcare Programs for its own presumptive and definitive testing using its in-house LCMS machine rather than referring those tests to an outside lab.

117. As the chart below illustrates, immediately after CIPS acquired its in-house LCMS machine, it dramatically increased its use of UDT. Between 2015 and the second quarter of 2018, CIPS performed presumptive UDTs in-house and referred definitive UDTs to third parties. This chart captures the total presumptive and definitive UDTs ordered for UDT patients, showing that fewer than 1000 total tests were performed per quarter prior to the second quarter of 2018. The amount of testing CIPS ordered increased dramatically after CIPS acquired its LCMS machine in the third quarter of 2018 (shown in red). After that date, CIPS routinely ordered well over 2000 tests per quarter for its patients. Thus, once CIPS had the ability to bill directly for (and receive the payment for) LCMS-based UDT screening, it more than doubled the rate at which it ordered those tests.



118. In April 2019, a Unified Program Integrity Contractor performed an audit ("Medicare Audit") of 10 CIPS locations on behalf of Medicare. The purpose of this audit was to determine if CIPS was billing for urine drug testing that was not reasonable and necessary. The audit reviewed a sample of 125 claims for UDT services CIPS performed between July 2, 2018, and December 31, 2018.

119. The Medicare Audit found that 98.4% of the claims for payment for UDTs submitted by CIPS—*i.e.*, all but 2 of the claims reviewed—were ineligible for payment because they were either medically unnecessary or the medical records did not include sufficient documentation supporting medical necessity . Medicare subsequently recovered this overpayment from CIPS.

120. Similarly, in September 2020, AmeriHealth Caritas, a private health insurer, performed an audit ("AmeriHealth Audit") of claims submitted by CIPS for UDT services

provided between October 5, 2018, and April 28, 2020. The AmeriHealth Audit reviewed 408 claims submitted by CIPS for presumptive and definitive UDT. The AmeriHealth Audit found a 100% error rate and concluded that none of the claims for UDTs submitted by CIPS should have been reimbursed because they were either medically unnecessary or the corresponding medical records did not include sufficient supporting documentation.

121. In July 2020, after the Medicare Audit, CIPS modified its UDT billing practices for Medicare patients by adding an "MDC" or Medicare testing panel ("Medicare Panel") for definitive testing. The Medicare Panel only tested for specific drug classes and corresponded with CPT Code G0481. CIPS began using this panel for all patients who were 65 and older and were categorized as high risk. However, even after introducing the Medicare Panel, CIPS' providers failed to individually risk assess their patients or place UDT orders. Instead, the UDS Techs continued to place orders for UDTs.

122. Indeed, upon information and belief, UDS Techs would routinely place orders for patients the day before those patients were scheduled for their clinical visits. The UDS Techs would submit those orders to Catalyst, the company that ran CIPS's LCMS lab, and subsequently inform Catalyst if any of the anticipated patients did not show for their appointments or were otherwise unable to provide a urine sample.

123. CIPS submitted or caused the submission of false claims by certifying that the UDTs for which it was seeking reimbursement were reasonable and necessary. CIPS knew, recklessly disregarded, or deliberately ignored the fact that the certifications were false because (i) the UDTs were ordered without properly risk assessing each patient; (ii) the medical necessity of the UDTs was not documented in the patient files; (iii) the UDTs were ordered by UDS Techs instead of physicians or medical providers; and (iv) the UDT results were not used for diagnosis or treatment.

124. Dr. Woo caused the submission of these false claims by developing and implementing the UDT Protocol that CIPS' employees used to submit false claims to the Federal Healthcare Programs, as identified above.

A. Illustrations - Testing and Billing for Patient V.C.

125. Patient V.C. provides an illustration of CIPS's fraudulent testing and billing practices under the UDT Protocol.

126. Between August 2018 and February 2021, a period of about 30 months, CIPS submitted claims for payment for 10 presumptive and 10 definitive UDTs for patient V.C.

127. In every clinical visit where V.C.'s previous UDT results were discussed, the physician indicated that V.C.'s UDT results were consistent. Despite this, V.C. was subject to repeated testing using the most comprehensive panel. V.C. was never risk assessed but was nevertheless categorized as "high risk" during this entire period.

128. The physicians' notes for V.C. include no documentation supporting the medical necessity for any of the UDTs, conflicting with the requirements of 42 C.F.R. § 410.32(d)(2). Further, because the definitive tests were ordered simultaneously with the presumptive tests, the definitive tests cannot have resulted from an inconsistent or unexpected result on a presumptive test.

129. V.C.'s medical records also include no indication that any physician ordered any of the testing, conflicting with 42 C.F.R. § 410.32(a). Further, V.C.'s medical records include no language showing the treating physician's intent to order lab tests. V.C.'s medical records also fail to include any documentation showing that the testing results were ever used for any treatment or diagnosis.

130. The eight definitive tests prior to July 2020 used the most expensive and expansive CPT Code of G0483. However, after the implementation of the Medicare Panel in July 2020, the

next two definitive tests were submitted using the lowest cost CPT Code of G0481. Nothing in V.C.'s medical records indicates that the less expansive test was a result of any change in V.C.'s clinical condition or risk profile. Defendants thus knew that it was unnecessary to test patient V.C. using the more expensive G0483 CPT code prior to July 2020.

131. Accordingly, CIPS submitted false claims for reimbursement for V.C. by certifying to the Federal Healthcare Programs that the UDTs ordered for V.C. was reasonable and necessary. CIPS knew, recklessly disregarded, or deliberately ignored the fact that the certifications that the UDTs were reasonable and necessary were false because (i) they were ordered without properly risk assessing V.C.; (ii) the tests' medical necessity was not documented in V.C.'s patient file; (iii) upon information and belief, the tests were ordered by a UDS Tech and not a physician or medical provider; and (iv) the test results were not used for diagnosis or treatment.

132. Dr. Woo caused these false submissions because CIPS submitted these claims pursuant to the UDT Protocol that he developed and implemented.

B. Illustrations - Testing and Billing for Patient S.B.

133. Similarly, between September 2019 and December 2021, CIPS submitted claims for 8 definitive and 8 presumptive UDT for patient S.B. Seven of the definitive tests were billed using CPT codes G0482 or G0483.

134. During seven clinical visits where S.B.'s previous UDT results were discussed, the physician indicated that S.B.'s UDT results were consistent. S.B. was never risk assessed during this period.

135. Despite this, the UDT ordered for S.B. was for a more comprehensive testing panel. Indeed, the only time S.B.'s UDT returned an inconsistent result, CIPS followed up with the less comprehensive Medicare Panel for S.B. And when the results of that Medicare Panel showed that

S.B. was once again consistent with her medication, CIPS reverted to ordering a more comprehensive panel, corresponding with a billing code of G0483, for the subsequent UDTs.

136. The physicians' notes for S.B. include no documentation supporting the medical necessity for any of the UDT, conflicting with the requirements of 42 C.F.R. § 410.32(d)(2). S.B.'s medical records also include no indication that any physician ordered the testing, conflicting with 42 C.F.R. § 410.32(a). Further, S.B.'s medical records include no language showing the treating physician's intent to order lab tests or that the results from the UDT were used for any diagnosis or treatment.

137. Accordingly, CIPS submitted false claims for reimbursement for S.B. by certifying to the Federal Healthcare Programs that the UDTs ordered for S.B. were reasonable and necessary. CIPS knew, recklessly disregarded, or deliberately ignored the fact that the certifications that the UDTs were reasonable and necessary were false because (i) they were ordered without properly risk assessing S.B.; (ii) the tests' medical necessity was not documented in S.B.'s patient file; (iii) upon information and belief, the tests were ordered by a UDS Tech and not a physician or medical provider; and (iv) the test results were not used for diagnosis or treatment.

138. Dr. Woo caused these false submissions because CIPS submitted these claims pursuant to the UDT Protocol that he developed and implemented.

C. Illustrations - Testing and Billing for Patient C.W.

139. As another example, between August 2018 and January 2021, CIPS submitted 8 definitive and 8 presumptive UDTs for patient C.W., *i.e.*, one definitive and one presumptive test every three months as dictated by CIPS' UDT Protocol. All definitive tests were billed using CPT codes G0482 or G0483.

140. Prior to CIPS opening its in-house lab in July 2018, CIPS ordered only one presumptive and one definitive UDT for C.W. for the 10-month period between September 2017

and July 2018. CIPS started ordering additional tests for C.W. shortly after it acquired its in-house lab. Nothing in C.W.'s medical records suggests any change in C.W.'s condition or risk profile that necessitated this increase in the frequency of testing.

141. In every clinical visit where C.W.'s previous UDT results were discussed, the physician indicated that C.W.'s UDT results were consistent. C.W. was never risk assessed during this period.

142. The physicians' notes for C.W. include no documentation supporting the medical necessity for any of the UDT, conflicting with the requirements of 42 C.F.R. § 410.32(d)(2). C.W.'s medical records also include no indication that any physician ordered the testing, conflicting with 42 C.F.R. § 410.32(a). Further, C.W.'s medical records do not show that the UDT results were used for any diagnosis or treatment.

143. Accordingly, CIPS submitted false claims for reimbursement for C.W. by certifying to the Federal Healthcare Programs that the UDTs ordered for C.W. were reasonable and necessary. CIPS knew, recklessly disregarded, or deliberately ignored the fact that the certifications that the UDTs were reasonable and necessary were false because (i) they were ordered without properly risk assessing C.W.; (ii) the tests' medical necessity was not documented in C.W.'s patient file; (iii) upon information and belief, the tests were ordered by a UDS Tech and not a physician or medical provider; and (iv) the test results were not used for diagnosis or treatment.

144. Dr. Woo caused these false submissions because CIPS submitted these claims pursuant to the UDT Protocol that he developed and implemented.

D. Illustrations - Testing and Billing for Patient L.G.-S.

145. As yet another example of CIPS' false billing practices for UDT, between June 2019 and January 2021, CIPS submitted 6 definitive and 6 presumptive UDTs for patient L.G.-S.

Five of the 6 definitive tests were billed using CPT code G0483. One definitive test, in October 2020, used the Medicare Panel and was billed using G0481. The next definitive test, in January 2021, once again used CPT code G0483.

146. In every clinical visit where L.G.-S.'s previous UDT results were discussed, the physician indicated that L.G.-S.'s UDT results were consistent. Despite this, L.G-S. was subject to repeated testing using comprehensive panels used for high risk patients under the UDT Protocol. L.G.-S. was never risk assessed during this period.

147. The physicians' notes for L.G.-S. include no documentation supporting the medical necessity for any of the UDTs, conflicting with the requirements of 42 C.F.R. § 410.32(d)(2). L.G.-S.'s medical records also include no indication that any physician ordered the testing, conflicting with 42 C.F.R. § 410.32(a). Further, L.G.-S.'s medical records do not show that the UDT results were used for any diagnosis or treatment.

148. Accordingly, CIPS submitted false claims for reimbursement for L.G.-S. by certifying to the Federal Healthcare Programs that the UDTs ordered for L.G.-S. were reasonable and necessary. CIPS knew, recklessly disregarded, or deliberately ignored the fact that the certifications that the UDT were reasonable and necessary were false because (i) they were ordered without properly risk assessing L.G.-S.; (ii) the tests' medical necessity was not documented in L.G.-S.'s patient file; (iii) upon information and belief, the tests were ordered by a UDS Tech and not a physician or medical provider; and (iv) the test results were not used for diagnosis or treatment.

149. Dr. Woo caused these false submissions because CIPS submitted these claims pursuant to the UDT Protocol that he developed and implemented.

DEFENDANTS' FRAUDULENT PSYCHOLOGICAL AND NEUROPSYCHOLOGICAL TESTING SCHEME

150. In or about 2019, CIPS began submitting claims for psychological and neuropsychological testing using CPT code 96138 that it knew, deliberately ignored, or recklessly disregarded were not reasonable and necessary and were inconsistent with the Medicare guidance for when psychological and neuropsychological testing was appropriate. Starting on or about January 1, 2019, and continuing through at least February 2021, CIPS billed Federal Healthcare Programs for CPT Code 96138 for nearly every patient visit.

151. At that time, CIPS began asking its patients to complete some combination of the following self-administered health screening questionnaires: AUDIT, DAST-10, GAD-7, PHQ-2 (collectively, "Screening Questionnaires"). As noted above, self-administered tests such as the Screening Questionnaires are not considered reasonable and necessary psychological or neuropsychological testing.

152. Further, CIPS did not use the Screening Questionnaires to diagnose mental illness or brain dysfunction or for the purpose of clarification for any diagnosis and treatment of patients. Indeed, it appears that CIPS did not use the Screening Questionnaires for any purpose related to treatment of its patients.

153. For example, as discussed in greater detail below, even when the Screening Questionnaires returned a result indicative or some illness or injury, no medical interventions or treatment plans were recommended by CIPS' clinicians to address patients' screening results.

154. Medicare guidelines are clear that providers may submit claims for "[a]lcohol and/or substance (other than tobacco) abuse structures screening (e.g., AUDIT, DAST), and brief intervention (SBI) services" only when they "are not provided as screening services, but … are performed in the context of the diagnosis or treatment of illness or injury." *Medicare Claims*

Processing Manual Chapter 4 § 200.6 Billing and Payment for Alcohol and/or Substance Abuse Assessment and Intervention Services, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf#page=169 (last visited June 3, 2024).

155. In total, from 2019 through 2023, Medicare paid CIPS almost $2 million for claims submitted under CPT Code 96138. Upon information and belief, other Federal Healthcare Programs also paid CIPS for claims submitted under CPT Code 96138.

156. Defendants submitted or caused to be submitted claims to Federal Healthcare Programs under CPT Code 96138 with knowledge, deliberate ignorance, or reckless disregard of the fact that CIPS providers were not conducting any psychological or neuropsychological testing covered by that code. Further, these claims were submitted with knowledge, deliberate ignorance, or with reckless disregard of the fact that CIPS providers not using the results of the Screening Questionnaires for any diagnostic or treatment purposes and that the services billed under CPT Code 96138 were therefore not reasonable and necessary.

A. Illustrations - Individual Patient Testing and Billing

157. Patient C.W. provides an illustration of CIPS's fraudulent psychological and neuropsychological testing and billing practices.

158. CIPS reported CPT Code 96138 for reimbursement from Medicare for patient C.W. for nearly every visit from February 7, 2020, to July 18, 2023, for a total of 46 claims. During several months, including March 2021, August 2021, September 2021, January 2022, and July 2022, CIPS reported CPT Code 96138 two or more times during the same month. On each occasion, C.W.'s medical records show that CIPS asked C.W. to complete the PHQ-2, GAD-7, DAST-10, and AUDIT questionnaires.

159. Further, on some service dates, such as February 5, 2021, C.W. reported feeling depressed every day on her PHQ-2 and reported feeling anxious every day on her GAD-7. These

results were never addressed or reported in C.W.'s progress note. Moreover, even though the GAD-7 includes a "Scoring" section for official coding purposes, the medical record shows that no score was calculated.

160. Patient R.E. provides another illustration of CIPS's fraudulent psychological and neuropsychological testing and billing practices.

161. CIPS reported CPT Code 96138 for reimbursement from Medicare for patient R.E. for nearly every visit from February 2020 to January 2021, for a total of 13 claims. On each occasion, R.E.'s medical records show that CIPS asked R.E. to complete the PHQ-2, GAD-7, DAST-10, and AUDIT questionnaires.

162. Further, on at least service date January 19, 2021, R.E. completed the GAD-7 questionnaire but the score was never tabulated. If R.E.'s scores had been tabulated, R.E. would have screened positive for anxiety. Despite this, R.E.'s GAD-7 score was not discussed or addressed in R.E.'s progress notes from R.E.'s January 19, 2021 encounter.

163. Patient K.B. provides another illustration of CIPS's fraudulent psychological and neuropsychological testing and billing practices.

164. CIPS submitted CPT Code 96138 for reimbursement to Medicare for nearly every visit by K.B. between February 2020 and December 2021 for a total of 24 submissions. On each occasion, K.B.'s medical records show that CIPS asked K.B. to complete the PHQ-2, GAD-7, DAST-10, and AUDIT questionnaires. The questionnaires were never discussed or addressed in K.B.'s progress notes.

FIRST CAUSE OF ACTION
Against CIPS and Dr. Woo
False Claims Act: Presenting and Causing False Claims – Unnecessary and Unreasonable UDT Furnished by CIPS (31 U.S.C. § 3729(a)(1)(A))

165. The United States re-alleges and incorporates by reference all Paragraphs of this Complaint set out above as if fully set forth here.

166. As detailed above, Defendants presented and/or caused to be presented materially false and fraudulent claims for payment or approval to the Federal Healthcare Programs for UDT that was not reasonable and necessary.

167. Specifically, CIPS submitted false claims by seeking payment for UDTs that were not reasonable and necessary or were otherwise not covered by Federal Healthcare Programs. The UDTs were not covered because (i) the UDTs were ordered without properly risk assessing each patient; (ii) the medical necessity of the UDTs was not documented in the patient files; (iii) the UDTs were ordered by UDS Techs instead of physicians or medical providers; and (iv) the UDT results were not used for treatment or diagnosis. CIPS knew, was recklessly indifferent, or deliberately ignored the fact that the UDTs were not reasonable and necessary or were otherwise not covered by Federal Healthcare Programs.

168. Dr. Woo knowingly caused the submission of these false claims because CIPS submitted these claims pursuant to the UDT Protocol that he developed and implemented.

169. The Federal Healthcare Programs paid CIPS for these materially false claims and thus sustained damages because of this wrongful conduct.

SECOND CAUSE OF ACTION
Against CIPS and Dr. Woo
False Claims Act: False Statements Material to False Claims –
Unnecessary and Unreasonable UDT Furnished by CIPS (31 U.S.C. § 3729(a)(1)(B))

170. The United States re-alleges and incorporates by reference all Paragraphs of this Complaint set out above as if fully set forth here.

171. As detailed above, during the relevant time-period, Defendants made, used, or caused to be made or used, false records and statements, material to a false or fraudulent claim.

172. Specifically, CIPS made, used, and caused to be made or used, false records and statements when it certified that the UDTs for which it was seeking reimbursement were reasonable and necessary. The certifications were false because (i) the UDTs were ordered without properly risk assessing each patient; (ii) the medical necessity of the UDTs was not documented in the patient files; (iii) the UDTs were ordered by UDS Techs instead of physicians or medical providers; and (iv) the UDT results were not used for treatment or diagnosis.

173. Dr. Woo knowingly caused the making and using of these false records because CIPS submitted these claims pursuant to the UDT Protocol that he developed and implemented.

174. CIPS and Dr. Woo made or used, or caused to be made or used, such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether they were false.

175. The false records or statements were material to the decision of Federal Healthcare Programs to pay the claims. The false certifications, including the certification that the services provided were reasonable and necessary, were a necessary condition of payment for the claims.

176. The Federal Healthcare Programs paid CIPS for these materially false claims and thus sustained damages because of this wrongful conduct.

THIRD CAUSE OF ACTION
Against CIPS and Dr. Woo
False Claims Act: Presenting and Causing False Claims – Unnecessary and Unreasonable Psychological and Neuropsychological Testing by CIPS
(31 U.S.C. § 3729(a)(1)(A))

177. The United States re-alleges and incorporates by reference all Paragraphs of this Complaint set out above as if fully set forth here.

178. As detailed above, Defendants presented and/or caused to be presented materially false and fraudulent claims for payment or approval to the Federal Healthcare Programs for

psychological and neuropsychological testing that was not performed or was not reasonable and necessary.

179. Specifically, Defendants' submissions were false because they sought reimbursement from Federal Healthcare Programs for CPT Code 96138 where no psychological or neuropsychological testing had been performed and/or where the testing performed was not reasonable and necessary. Further, these claims were false because Defendants did not use the responses to the Screening Questionnaires for any treatment or diagnosis.

180. Defendants knew or acted with reckless disregard or deliberate ignorance of the fact that they were not administering psychological or neuropsychological testing and that the testing was not reasonable and necessary because the results were not used for diagnosing or treating patients.

181. The Federal Healthcare Programs paid CIPS for these materially false claims and thus sustained damages because of this wrongful conduct.

FOURTH CAUSE OF ACTION
Against CIPS and Dr. Woo
False Claims Act: False Statements Material to False Claims – Unnecessary and Unreasonable Psychological and Neuropsychological Testing by CIPS (31 U.S.C. § 3729(a)(1)(B))

182. The United States re-alleges and incorporates by reference all Paragraphs of this Complaint set out above as if fully set forth here.

183. Defendants knowingly made, used, and caused to be made or used false records or statements material to false or fraudulent claims submitted to the United States, and payment of those false or fraudulent claims by the United States was a reasonable and foreseeable consequence of the Defendants' statements and actions.

184. These false records and statements included false certifications on provider enrollment forms and false and misleading representations on claim forms that claims for payment for psychological and neuropsychological testing by CIPS that were billed to Federal Healthcare Programs were reasonable and necessary, when, in fact, that testing was unnecessary and unreasonable.

185. Specifically, Defendants made, used, and caused to be made or used false records and statements by submitting claims for reimbursement from Federal Healthcare Programs for CPT Code 96138 where no psychological or neuropsychological testing had been performed and/or where the testing performed was not reasonable and necessary, and by failing to use the responses to the Screening Questionnaires for any treatment or diagnosis.

186. The Defendants made or used, or caused to be made or used, such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether they were false.

187. The false records or statements were material to the decision of Federal Healthcare Programs to pay the claims. The false certifications, including the certification that the services provided were reasonable and necessary, were a necessary condition of payment for the claims.

188. The United States paid CIPS for these materially false claims and thus sustained damages because of this wrongful conduct.

FIFTH CAUSE OF ACTION
Against CIPS
Payment by Mistake – Unreasonable and Unnecessary Services

189. The United States re-alleges and incorporates by reference all Paragraphs of this Complaint set out above as if fully set forth here.

190. This is a claim for the recovery of monies paid by Federal Healthcare Programs to Defendant CIPS as a result of mistaken understandings of fact.

191. Federal Healthcare Programs paid CIPS for UDT and Psychological and Neuropsychological testing that did not comply with the requirements of the Federal Healthcare Programs. Federal Healthcare Programs made these payments without knowledge of material facts and under the mistaken belief that CIPS was entitled to receive payment for such claims when it was not. Federal Healthcare Programs' mistaken beliefs were material to its decision to pay CIPS for such claims. Accordingly, CIPS is liable to make restitution to the United States of the amounts of the payments made in error to CIPS by the Federal Healthcare Programs.

SIXTH CAUSE OF ACTION
Against CIPS and Dr. Woo
Unjust Enrichment

192. The United States re-alleges and incorporates by reference all Paragraphs of this Complaint set out above as if fully set forth here.

193. This is a claim for the recovery of monies by which Defendants have been unjustly enriched during the relevant time period at the expense of Federal Healthcare Programs.

194. By directly or indirectly obtaining government funds to which they were not entitled, the Defendants each were unjustly enriched, and are liable to account for and pay as restitution such amounts, or the proceeds therefrom, which are to be determined at trial, to the United States.

PRAYER FOR RELIEF

The United States demands and prays that judgment be entered in its favor against Defendants as follows:

A. On Counts I through IV under the False Claims Act, for the amount of the United States' damages, trebled as required by law, plus costs of investigation and prosecution, and such civil penalties for each false claim as are provided by law, plus interest, together with such further relief as may be just and proper.

B. On Count V for payment by mistake, against Defendant CIPS, for the damages sustained and/or amounts by which CIPS was paid by mistake or by which CIPS retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

C. On Count VI for unjust enrichment, for the damages sustained and/or amounts by which Defendants were unjustly enriched or by which Defendants retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

D. Pre- and post-judgment interest, costs, and such other relief as the Court may deem appropriate.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Respectfully submitted,

DAVID C. WEISS
United States Attorney

/s/ Shamoor Anis
Shamoor Anis
Jacob Laksin
Assistant U.S. Attorneys

Dated: June 17, 2024